

REMARKS

The present paper is presented in response to the office action dated August 15, 2008. This paper is being filed with a petition and fee for a three-month extension of time to respond and as such, the response is timely filed on February 16, 2009 by virtue of February 15, 2009 being a Sunday.

A. Status of the Claims

Claims 21, 22 and 24-31 were pending in the instant application. Claims 21, 22 and 23-31 were rejected under 35 U.S.C. 112 first paragraph for allegedly lacking written description. Claims 25 and 30 were rejected under 35 U.S.C. 102(b) as allegedly anticipated by the disclosure of WO 92/21375 and claims 21, 22 and 23-31 were rejected under 35 U.S.C. 103 over a combination of WO 92/21375 and Moorman et al (J. Virology, vol 70, pages 763-770).

Claims 21, 22, 24, 25, 26, 28 and 30 have been amended. Claims 27, 29 and 31 have been cancelled and claims 32-37 are newly presented.

B. Rejection under 35 U.S.C. 112, first paragraph

Claims 21, 22 and 23-31 were rejected under 35 U.S.C. 112 first paragraph as allegedly failing to comply with the written description requirement. According to the examiner, while SEQ ID NO:18 is described "Applicant has not taught where to find additional members of the genus and applicant has not shown possession of sufficient members of the genus to have possession of the claimed genus."

As noted in the specification “[a]n infectious cDNA clone has not been described for Arteriviruses so far.” (page 10, ¶0029). The invention goes on to report how to generate infectious clones of PRRS virus, to wit: “[t]he utmost 5’ end was incorporated in genome-length cDNA to creat an infectious clone.” (page 23, ¶0055) The sequence of the utmost 5’ end is given as SEQ ID NO:18 (see page 23, ¶0054). The sequences of PRRS virus strains that are non-infectious were known to those of skill in the art and were described in the specification according to publicly deposited accession numbers. For example, at page 4 ¶0008, PRRS virus strains deposited under accession number CNCM I-1102, I-1140, I-1387, ECACC V93070108, ATCC VR 2332, ATCC VR 2385, ATCC VR 2386, ATCC VR 2429, ATCC VR 2474 and ATCC VR 2404 are taught.

The reference to these deposits is sufficient to show that applicants had possession of the invention in accordance with Federal Circuit precedent which provides that disclosure of a nucleic acid by reference to a biological deposit is sufficient to meet written description requirement. *Enzo Biochem v. Gen-Probe*, 63 USPQ2d 1618 (Fed. Cir. 2002). In *Enzo*, the Federal Circuit held that reference in the specification and claims to a deposit in a public depository constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of 35 U.S.C. §112 stating that “In light of the history of biological deposits for patent purposes, the goals of the patent law, and the practical difficulties of describing unique biological materials in a written description, **we hold that reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form,**

constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1.” 2002 WL 32036710 at *5 (emphasis added).

In view of the claim amendments and the Federal Circuit precedent in *Enzo*, Applicants believe that the claims as presented above meet the written description requirement and request that the rejection be withdrawn.

C. Rejection under 35 U.S.C. 102(b)

Claims 25 and 30 were rejected under 35 U.S.C. 102(b) as anticipated by WO 92/21375. Applicants have amended the claims to specifically recite the presence of SEQ ID NO:18 at the 5' end of sequences of PRRS viruses of specific deposits. Applicants believe this claim amendment overcomes the rejection under 35 U.S.C. 102(b) because WO 92/21375 does not teach wild-type PRRS virus sequences that have been modified to contain a sequence (SEQ ID NO:18) that renders those viruses infectious.

Applicants request reconsideration of the rejection.

D. Rejection under 35 U.S.C. 103(a)

Claims 21, 22 and 23-31 were rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over WO 92/21375 in view of Moormann et al (J. of Virology, Vol 70 pp 763-770). Applicants respectfully disagree with the Examiner.

The claims as presented are directed to specific nucleic acids and infectious species from PRRS virus strains deposited under accession number CNCM I-1102, I-1140, I-1387, ECACC V93070108, ATCC VR 2332, ATCC VR 2385, ATCC VR 2386, ATCC VR 2429, ATCC VR 2474 and ATCC VR 2404 that are rendered infectious by having inserted at their 5' end a specific sequence that generates infectious species.

WO 92/21375 provides the basic disclosure of the nucleic acid sequence of a PRRS virus strain. However, nowhere in WO 92/21375 is there a teaching that it would be desirable to include a specific sequence of SEQ ID NO:18 at the 5' end of the virus genome to render that genome infectious. Likewise, Moormann et al. fails to provide any guidance as to why a sequence of SEQ ID NO:18 as opposed to any other sequence would be particularly useful in rendering a PRRS virus infectious. Thus, the teachings of the prior art are inadequate for rendering specifically claimed sequences obvious.

While the prior art, including WO 92/21375, may well have identified various PRRS viruses, as specifically noted in the specification, routinely infectious clones of such viruses were not described (page 10, ¶0029). It was the teachings of the present invention that showed that incorporating a sequence of SEQ ID NO:18 into the utmost 5' end into genome-length cDNA of those viruses to create infectious clones. With this teaching it is now possible to generate infectious clones of viruses known in the art. Such viruses can then be used as delivery vehicles for generating an immune response.

In view of the above discussion, Applicants believe the rejection of claims 21, 22 and 23-31 were rejected under 35 U.S.C. 103(a) should be withdrawn.

E. Closing Remarks

Applicants believe the above remarks and amendments overcome the outstanding rejections and Applicants request withdrawal of the rejections and reconsideration of the claims for allowance. No additional fees are believed to be due, however, should fees be deemed necessary or should there be an overpayment, the Commissioner is authorized to charge any additional fees or credit any overpayment to the Deposit Account of McAndrews, Held & Malloy, Account No. 13-0017.

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Respectfully submitted,

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